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**IN THE**
***SUPREME COURT OF THE UNITED STATES***
**OCTOBER TERM, 1992**

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WILLIAM DAUBERT and JOYCE DAUBERT, Individually and As Guardians Ad Litem for JASON DAUBERT, and ANITA DE YOUNG, Individually and As Guardian Ad Litem for ERIC SCHULLER,

*Petitioners,*

*v.*

MERRELL DOW PHARMACEUTICALS, INC.

*Respondent.*

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PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

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# BRIEF *AMICI CURIAE* OF PROFESSORS KENNETH ROTHMAN, NOEL WEISS, JAMES ROBINS, RAYMOND NEUTRA AND STEVEN STELLMAN, IN SUPPORT OF PETITIONERS

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## INTEREST OF *AMICI CURIAE*

*Amici* are teachers and scholars of epidemiology. Dr. Rothman, the Editor of the journal *Epidemiology*, and a member of the Editorial Board of the *New England Journal of Medicine*, currently serves as Professor of Public Health (Epidemiology and Biostatistics) at the Boston University School of Medicine and Public Health, Adjunct Professor of Epidemiology at the Harvard School of Public Health, and Senior Epidemiologist at Epidemiology Resources Incorporated. Dr. Weiss, the author of 185 publications in the field of epidemiology, is Professor and Chairman of the Department of Epidemiology, School of Public Health and Community Medicine, at the University of Washington. Dr. Robins, Associate Editor of the *American Journal of Epidemiology*, is a Professor of Epidemiology and Biostatistics at the Harvard School of Public Health. Dr. Neutra, a past president of the International Society for Environmental Epidemiology, currently serves as Lecturer in Epidemiology at the University of California School of Public Health, Chief of the Exposure Assessment Section of the California Department of Health Services, and Acting Chief of the Environmental Health Investigations Branch of the California Department of Health Services.[1] Dr. Stellman, the author of over 60 papers in epidemiology and health sciences, currently serves as Senior Research Scientist at the American Health Foundation (where he is chief epidemiologist for studies of tobacco-related cancers), an NIH Fogarty International Fellow at the International Agency for Research on Cancer in Lyon, France, and Adjunct Associate Professor of Community Medicine at the Mount Sinai School of Medicine. More complete biographies of the *amici* appear in the Appendix to this brief.

As part of our professional duties we routinely apply the principles of epidemiology to address a wide variety of public health issues in conjunction with, and not isolated from, other traditional areas of science. *Amici* appear on their own behalf to address matters that intimately affect and threaten to alter the role

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[1] Dr. Neutra is appearing as *amicus* in his own behalf and not as a representative of any governmental agency.

of epidemiological concepts in science -- an interest that transcends the perspectives of the parties in this case and that might not otherwise be brought to the Court's attention.[2]

## SUMMARY OF ARGUMENT

We have each read the decisions of the trial court and appellate court in this case. We are practicing scientists, not lawyers. We cannot and do not opine as to legal issues such as whether federal judges have the authority to supplement enacted rules for excluding evidence. Rather, we write to explain how the lower courts have misconstrued the role of epidemiology, and its limits and scope, in modern science.

Science fulfills many functions in our society. As practitioners of a discipline that seeks, but never finds, absolute truth, scientists use a variety of criteria to evaluate data in conditions that provide less than total certainty. The purpose of this brief is to demonstrate to the Court that the lower court opinions reflect a misunderstanding of scientific decision making within the context of epidemiology.

In conveying to the Court the position of *amici*, no position is taken as to whether Bendectin can be said to be a legal cause of birth defects in children. Rather, the function of this brief is to illuminate epidemiologic practices and principles that were poorly understood by the lower courts in this case. The lower courts' blind deference to inappropriate and arcane publication standards and "significance testing," reflecting methodologies held to be unacceptable by *amici* as well as many other practicing epidemiologists, will prevent valuable information from reaching legal factfinders in at least three ways. First, the standard imposed by the trial court totally misconstrues the validity and appropriateness of significance testing as a decision making tool, apparently deeming it the sole test of epidemiological

[2] Counsel to the parties have consented to the filing of this brief. Letters of consent have been filed with the Clerk.



hypotheses. Significance testing, however, is neither necessary nor appropriate as a requirement for drawing inferences from epidemiologic data. Second, by focusing on inappropriate criteria applied to determine what conclusions, if any, can be reached from any one study, the trial court forecloses testimony about inferences that can be drawn from the combination of results reported by many such studies, even when those studies, standing alone, might not justify such inferences. Third, by suggesting that an expert's "reanalysis" of published data is suspect unless itself published, the appellate court fundamentally misconstrues how epidemiologists in the real world of science function on a daily basis. Thus, the lower courts' standards prevent factfinders from learning about inferences that can be drawn from published data using generally accepted techniques.

## ARGUMENT

### I. THE LOWER COURTS' FOCUS ON SIGNIFICANCE TESTING IS BASED ON THE INACCURATE ASSUMPTION THAT "STATISTICAL SIGNIFICANCE" IS REQUIRED IN ORDER TO DRAW INFERENCES FROM EPIDEMIOLOGICAL INFORMATION.

The notion that only when data demonstrate "statistical significance" do epidemiologists draw inferences about observed associations between suspected risk factors and medical conditions is mistaken. Significance testing is nothing more than a statistical technique that attempts to evaluate what is called "chance" as a possible explanation for a set of observations, and classify the observations "significant" or "not significant" based on the likelihood of observing them if there were no relationship between the suspected cause and effect. Testing for significance, however, is often mistaken for a *sine qua non* of scientific inference.

It is crucial that this Court understand the distinction between these two separate and distinct processes. Scientific inference is the practice of evaluating theories. As such, it is a

thoughtful process, requiring thoughtful evaluations of possible explanations for what is being observed. Significance testing, on the other hand, is merely a statistical tool that is frequently, but inappropriately, utilized in the process of developing inferences.

Until recently, most epidemiologists were physicians. Their interest in epidemiology was focused on the occurrence patterns of a given disease. In doing so, these physicians have collaborated with statisticians who contributed expertise in making observations on large populations as well as in data analysis. As a result, much of the theoretical development of modern epidemiology has been contributed by statisticians -- Cornfield, Mantel, Cox, Breslow and Prentice -- to name but a few of the outstanding contributors. It was natural for statisticians to rely on methods of statistical analysis with which they were familiar in other areas of application. These methods have become incorporated into epidemiologic practices. Of these methods, significance testing has come to dominate and influence epidemiological practices to such an inordinate extent that undue reliance is often placed on its role in epidemiologic data analysis. Significance testing serves, however, merely as a tool for epidemiologists to achieve their scientific objectives. Indeed, the term "statistical significance" could be expunged from the lexicon of the epidemiologist with no loss; accordingly it should not be allowed to assume an importance or role in law beyond its use as an epidemiological tool. When used to evaluate the association between exposure and disease, the concept of statistical significance is often misleading and never descriptive of the magnitude of effect or the precision of measurement. Nonetheless, a factfinder who is told that a body of data is not "statistically significant" is made to believe that the data has no value. Unfortunately, the seemingly talismanic phrase "statistically significant" creates a misleading aura of infallibility totally out of relation to its actual value.

It should be noted that the motivation for the development of statistical hypothesis testing was to provide a basis for decision making in agriculture and quality-control experiments. These experiments were designed to answer questions that called for



specific actions; accordingly, the results had to be classified, if possible, into qualitatively discrete categories. Thus arose the practice of declaring associations in data as "statistically significant" or "nonsignificant" using arbitrary criteria that became conventions. Undue reliance on statistical significance (instead of more general tools of scientific inference) has resulted in, for example, the overlooking of effective new treatments because their effects were judged to be "not significant' despite the presence of an indication of efficacy in the data. Thus, testing for statistical significance, a methodologic tool, has become for some a clumsy substitute for thought, subverting what should be a contemplative thoughtful exercise into an algorithm prone to error.

It is noteworthy that the role of significance testing has been questioned by many over a long period of time. In 1970, Morrison and Henkel published a book entitled "The Significance Test Controversy" (Aldine Publishing Company, Chicago) which challenged the emerging orthodoxy of mandating that statistical significance be a central bastion of any scientific pronouncement. Several years earlier, significance testing was derided as an American obsession:

> No formal tests of significance can answer those questions. ("Is there any other way of explaining the set of facts before us, is there any other answer equally, or more, likely than cause and effect?") Such tests can, and should, remind us of the effects that the play of chance can create, and they will instruct us in the likely magnitude of those effects. Beyond that they contribute nothing to the 'proof' of our hypothesis." ******* "I wonder whether the pendulum, has not swung too far -- not only with the attentive pupils, but with the statisticians themselves . . . Fortunately I believe we have not yet gone so far as our friends in the USA where, I am told, some editors of journals will return an article because tests of significance have not been applied. . .

Austin Bradford Hill, *The Environment and Disease - Association or Causation?*, Proceedings of the Royal Society of Medicine (1965) 58:296-300, at 299.

Significance testing, in the view of *amici* and many other respected scientists, places too high a value on a "yes-no" answer to an oversimplified question: Is the probability that the observed association could appear by chance, even if there is no actual relationship, low enough to justify rejection of chance as the explanation of the observed association? The result of using significance testing as the criterion for decision making is that the focus is changed from the information presented by the observations themselves to conjecture about the role chance *could* have played in bringing about those observations.

One *amicus* has observed:

> With the focus on statistical significance, if chance seems to be a plausible explanation, then other theories are too readily discarded, regardless of how tenable they may be. As a result, effective new treatments have often been overlooked because their effects were judged to be "not significant," despite an indication of efficacy in the data. Conversely, if "significance" seekers find that the results of a study are calculated as improbable on the basis of chance, then chance is often rejected as an explanation when alternative explanations are even less tenable.

K. Rothman, *Significance Questing*, 105 Annals of Internal Medicine 445, 445-46 (1986) (citations omitted).

It is important to note that while, in this case, the lower courts' deference to significance testing resulted in the improper rejection of valuable information, that same undue deference could lead, in a different case, to accepting unwarranted hypotheses. For example, would any reasonable scientist accept the proposition that wearing a dress is causally related to the occurrence of breast cancer simply because the association



between the two is statistically significant? Of course not, but such is the possible misapplication of significance testing that flows from the pervasive and fundamental misunderstanding of its use.

A better approach to evaluating the error in scientific measurement is the use of "confidence intervals." A confidence interval is a range of possible values for a parameter that is consistent with the observed data within specified limits.[3] The process of calculating a confidence interval within the chosen limits is know as "interval estimation." See K. Rothman at 119.

An important advantage of interval estimation is that it:

> do[es] not require irrelevant null hypothesis to be set up nor [does it] force a decision about "significance" to be made -- the estimates can be presented and evaluated by statistical *and other* criteria, by the researcher or the reader. In addition the estimates of one investigation can be compared with others. While it is often the case that different measurements or methods of investigation or theoretical approaches lead to "different" results, this is not a disadvantage; these differences reflect important theoretical differences about the meaning of the research and the conclusions to be drawn from it. And it is precisely those differences which are obscured by simply reporting the significance level of the results.

L. Atkins and D. Jarrett, The Significance of "Significance Tests," in J. Irvine and I. Miles (eds.) *Demystifying Social Statistics* (1979). Indeed, the Court of Appeals for the Third Circuit has recognized that confidence intervals could prove to be a more acceptable basis for legal decision making than

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[3] For an analysis of confidence intervals in the legal context, see N. Cohen, *Confidence in Probability: Burdens of Persuasion in a World of Imperfect Knowledge*, 60 N.Y.U.L.Rev. 385 (1985).

significance testing. *DeLuca v. Merrell Dow Pharmaceuticals, Inc.*, 911 F.2d 941, 945-949, 953-957 (3d Cir. 1990).

It is necessary for this Court to be aware that there is a large community of respected epidemiologists that rejects the single-minded focus on significance testing that is expressly mandated by the trial court and implicitly adopted by the appellate court, without the benefit of expert testimony or analysis memorialized in its opinion. As an example, *Epidemiology* (an epidemiology journal of which *amicus* Dr. Rothman is editor) discourages publication of articles that rely on significance testing. Recognizing this divergence of opinion, this Court should reject significance testing as the sole acceptable criterion of scientific validity in epidemiology. Just as the lexicon of the epidemiologist should be improved by expunging references to statistical significance, that term should be removed from the inappropriate legal pedestal, remote and separate from reality, on which it was placed by the lower courts.

## II. THE APPELLATE COURT'S SKEPTICISM ABOUT "REANALYSIS" IS UNFOUNDED AND FORECLOSES EXPERTS FROM DRAWING INFERENCES FROM ALL AVAILABLE INFORMATION

### A. "Reanalysis" is a Generally Accepted Methodology Within Science, Including in the Field of Epidemiology

The suggestion of the appellate court to the contrary, "reanalysis" in regards to epidemiology is not foreign to epidemiology, but essential to it -- for it is the principal mode of the "replication" that is fundamental to science and so lauded by the appellate court. "Replicating" is the process by which one scientist tries to verify the procedures and analyses undertaken by other scientists. In some disciplines, such as chemistry and subatomic physics, it is possible to replicate from scratch the exact experiment conducted by the first scientist. In other situations, the expense involved, or the existence of ethical constraints, limits the second scientist only to analysis of the data



accumulated by the first scientist or by other scientists; new data cannot be collected. For example, an epidemiologist is not in a position to expose a million workers to asbestos, or a million women to DES, to test the etiology of diseases caused by these products. An epidemiologist in such cases is restricted to studying the information available, no matter how limited, and inevitably must engage in "reanalysis" of existing data.

In an apparent effort to devise a bright-line rule, the court below has erected a false dichotomy. According to the appellate court, "analysis" takes place when an epidemiologist collects his or her own underlying data and develops inferences from it, and publishes or otherwise circulates the study, whereas "reanalysis" occurs whenever any other scientist looks at that study, alone or in combination with other published articles or other non-published studies, and expresses his or her own inferences from the larger universe of data. The appellate court's suggestion that reanalysis of epidemiological studies is something unusual, deserving more than other scientific techniques to be scrutinized skeptically, is simply wrong. In fact, reanalysis, even as defined by the lower court, is not an arcane or specialized enterprise; rather, this is the everyday work of the practicing epidemiologist in fields of public health.

In analyzing all available data and evaluating different theories that might explain such data, scientists not only assay the conventional wisdom but the unorthodox wisdom as well. By contrast, implicit in the appellate court's holding is that when the *conclusion* of an epidemiologist from a body of data differs from that reached by another epidemiologist who has published his or her conclusions, something unusual is occurring, and that the dissenting epidemiologist's views are inherently suspect. This is a dangerous course because it risks shutting off serious inquiry into important scientific issues at a superficial level. For example, the appellate court opines that the methodology of "reanalysis" is "particularly problematic in light of the massive weight of the original published studies supporting the defendant's position, all of which had undergone full scrutiny from the scientific community." *Daubert v. Merrell Dow*

*Pharmaceuticals, Inc.*, 951 F.2d 1128, 1130 (9th Cir.1991). This "massive weight" is thought to flow from the fact that "no published epidemiological study had demonstrated a statistically significant association between Bendectin and birth defects." *Id.* at 1129.

Without expressing a position on the ultimate issue of the toxicity of Bendectin, it is obvious to us that no "massive weight" or sense of consensus can flow from the observation that a number of studies have been published involving Bendectin and that the authors of those studies did not infer *a "statistically significant association."* To give weight to the failure of epidemiological studies to meet strict "statistical significant" standards -- to use such studies to close the door on further inquiry -- is not good science. In fact, as discussed in Part I, it is both bad science and bad policy. *Amici* respectfully incorporate the positions as set forth in Section I, *supra*, as to why mindless adherence to significance testing is bad science.

### B. The analysis employed by the lower courts forecloses the use of valid inferences that may be drawn from the combination of many studies, even when none of the studies standing alone would justify such inferences.

Empirical research quite often yields data that suggest an association between a suspected risk factor and a medical condition, but with too small a data set to proclaim confidently that the observed association is real, and not merely the result of random factors. If the observed association resulted by chance, one would not expect to see it consistently replicated in studies of similar scope. If, on the other hand, the observed association reflects a real relationship, one would expect to see consistent results in studies of similar scope.

This commonsense observation is not novel or controversial, yet the opinion of the appellate court forecloses analysis based on it. To the extent that the lower courts' opinion bars expert opinions not based on published conclusions, that



opinion removes relevant information from the legal decision maker. That valuable information would be lost by such an exclusion can easily be illustrated by reference to presidential election polls. Assume that two days before the election, several major polls showed the challenger leading the incumbent, but by margins that were within each poll's margin of error. That is, the challenger's lead, based on the sample of voters questioned by each pollster, was not "statistically significant" at the threshold level employed by those polls. Thus, each pollster declined to conclude, based on its own data, that the challenger was in the lead. Nonetheless, a rational observer, noting that the chasllenger had a similar lead in each poll, would conclude that he was, in fact, in the lead. Why? Because the observer has implicitly pooled the data to reach a conclusion that the separate pollsters, describing only their part of the data could not reach.

The lower courts' decisions would foreclose this analysis. As other courts have recognized, foregoing the benefit of inferences that could be reached this way is inappropriate:

> A word about our approach to the evidence may be in order. Contrary to the apparent suggestion of some of the petitioners, we need not seek a single dispositive study that fully supports the Administrator's determination. Science does not work that way; nor, for that matter, does adjudicatory factfinding. Rather, the Administrator's decision may be fully supportable if it is based, as it is, on the inconclusive but suggestive results of numerous studies. By its nature, scientific evidence is cumulative: the more supporting, albeit inconclusive evidence available, the more likely the accuracy of the conclusion. If, as petitioners suggest, one single study or bit of evidence were sufficient independently to mandate a conclusion, there would, of course, be not need for any other studies. Only rarely, however, is such a limited study sufficient. Thus, after considering the inferences that can be drawn from the studies supporting the Administrator, and those opposing

> him, we must decide whether the cumulative effect of all this evidence, and not the effect of any single bit of it, presents a rational basis for [the regulation in question].

*Ethyl Corporation v. Environmental Protection Agency*, 541 F.2d 1 (D.C. Cir. 1976) (*en banc*).

Thus, to the extent that the opinion of the appellate court would bar consideration of the cumulative effect of many studies, even when none of them individually is "statistically significant," it should be rejected on the basis that such a conclusion is scientifically inappropriate.

## III. INFERENCES DRAWN FROM EPIDEMIOLOGIC REANALYSES ARE NOT SCIENTIFICALLY INVALID JUST BECAUSE THEY ARE NOT PUBLISHED IN PEER REVIEW JOURNALS

The appellate court is incorrect in suggesting that scientists have confidence in such "reanalysis," only if it is formally peer reviewed and published. To the contrary, only some of the conclusions drawn from such reanalyses are ever pul lished. Practicing scientists rely more often on informal exchange of papers, conversations, symposia, etc., in identifying new problems and in challenging consensus. Publication in peer-review journals obviously helps djsseminate those views further, and is an aid to a scientist's career (particularly in the academic arena), but peer-reviewed publications have never functioned as either reliable predictors or sole guarantors of scientific truth, as the appellate court seems to assume. It is the close and repeated questioning of all available scientific information on a given issue, and of the "accepted wisdom" on that issue, rather than consensus alone, that is the engine of scientific progress and the determinant of particular scientific truths. This is the type of "replication and verification" at the heart of "good science." Any decision maker responsible for resolving an issue of scientific fact should have available all sources of information that shed light on what may be considered the "consensus" view



in a given scientific field.

Were we on a jury in a civil trial, *amici* would wish to have access to the same sources we consult as practicing scientists. We would want to know all the facts, not just the truncated "consensus." The standard adopted by the appellate court would bar epidemiology experts from presenting to legal factfinders key information of the kind that on which they routinely rely on and communicate to other scientists in discharging important regulatory and other public health duties. Every new scientific idea, at its inception, is unpublished. These ideas may be nurtured through discussions, symposia and other means of communication without peer review publication. This is the way of science as it evolves towards, but never obtains, absolute truth.

## CONCLUSION

The opinions of the trial court and the appellate court demonstrate a fundamental misunderstanding of the role and the function of epidemiology in contributing helpful information to complex scientific questions. *Amici* respectfully request that this Court re-establish appropriate standards and methodology consistent with the points as set forth in this brief.

Respectfully submitted,

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# APPENDIX

## IDENTIFICATION OF AMICI CURIAE

**Dr. Rothman** was born in New York City in 1945, and attended public schools in Long Beach, New York. His undergraduate studies were at Colgate University, and his graduate work was at Harvard University. After receiving his Doctor of Public Health degree from Harvard in 1972, Dr. Rothman remained at the Department of Epidemiology at Harvard for 12 years as a faculty member. During these years he conducted research on the epidemiology of cancer and birth defects; he also taught advanced courses and wrote numerous papers on epidemiologic concepts and methods. For five years he was Professor of Family and Community Medicine at the University of Massachusetts Medical School. Currently he holds academic appointments as Professor of Public Health (Epidemiology and Biostatistics) at the Boston University Schools of Medicine and Public Health, and Adjunct Professor of Epidemiology at the Harvard School of Public Health. He also serves as a Senior Epidemiologist at Epidemiology Resources Incorporated.

Dr. Rothman has given advanced courses in epidemiologic concepts and methods by invitation in many universities in the U.S. and abroad, and he teaches a popular course each summer at the New England Epidemiology Institute. He is the author of a textbook of epidemiologic methods, *Modern Epidemiology*, which was published in 1986 and is now in its fifth printing. He has served for 12 years as a member of the Editorial Board of the *New England Journal of Medicine*; he has also served as Assistant Editor of the *American Journal of Public Health* and as Editor of the *American Journal of Epidemiology*. He now devotes much of his professional effort to his duties as Editor of *Epidemiology*.

**Dr. Weiss** has been the Chairman of the Department of Epidemiology, School of Public Health and Community Medicine, University of Washington in Seattle, Washington since

July 1984. His undergraduate studies were at Stanford University, and he obtained an M.D. Degree at Stanford University in 1967. He received a Masters and Doctor of Public Health Degree at Harvard School of Public Health in 1969 and 1971, respectively. His field of study was Epidemiology. Following the completion of his education, he was an epidemiologist at the Office of Health Statistics Analysis, National Center for Health Statistics in Rockville, Maryland. For three years he was the Head of the Cancer Surveillance System Program in epidemiology and biostatistics at the Fred Hutchinson Cancer Research Center in Seattle, Washington. His research and writing in the field of epidemiology include a total of 185 publications. Since July, 1979, he has been a Professor in the Department of Epidemiology, School of Public Health and Community Medicine at the University of Washington.

During all of these years Dr. Weiss has conducted research on the epidemiology of various disease processes, including the relationship between occupation and the occurrence of testicular cancer, tubal sterilization and subsequent ectopic pregnancy, exogenous estrogens and the risk of endometrial cancer, the prevalence of diabetes and impaired glucose tolerance among Navajo Indians, risk factors for tubal infertility, to name but a few areas of research. He has also taught advanced courses and written numerous papers on epidemiologic concepts and methods. Additionally, he has received research grants in epidemiology and biostatistics and has been actively involved in the Fred Hutchinson Cancer Research Center, Seattle, Washington, since 1974, first as an Assistant Member (January, 1974-June, 1976), Associate Member (July, 1976-June, 1982), and Member (July, 1982-present).

**Dr. Robins** is a Professor of Epidemiology and Biostatistics at the Harvard School of Public Health. His undergraduate studies were at Harvard where he achieved distinction in mathematics (Phi Beta Kappa). He received his M.D. degree from Washington University School of Medicine in 1976. Dr. Robins was an Intern in Internal Medicine at Harlem Hospital Center, New York (1976-77), a Resident in the Department of



Internal Medicine at Yale University School of Medicine (1978-80), and a Fellow in Preventive Medicine, Department of Epidemiology and Public Health, Yale University School of Medicine (1980-81). He was an Associate Director, at the General Occupational Health Clinic, Yale University Department of Internal Medicine (1979-82). and a Consultant in Occupational and Environmental Health to the Connecticut State Department of Health Services (1981-83). Dr. Robins was an Assistant Professor of Biostatistics, Harvard School of Public Health (1986-87), Assistant Professor of Occupational Health, Harvard School of Public Health (1982-87) and Associate Professor of Occupational Health and Biostatistics, Harvard School of Public Health (1987-1992)

His research and writing in the fields of biostatistics and epidemiology include a total of 51 publications. Many of these papers dealt with advanced concepts and methods in epidemiology. Dr. Robins is board certified in Internal Medicine (1980) and is a member of several organizations relevant to the fields of biostatistics and epidemiology. He has received grants as the Principal Investigator for various areas of biostatistics research. He has taught advanced courses in epidemiologic methods and occupational and environmental epidemiology at the Harvard School of Public Health. He serves as an Associate Editor for the *American Journal of Epidemiology*.

**Dr. Neutra** was born in Los Angeles in 1939. He received his B.A. degree at Pomona College, Claremount, California (1961), M.D., C.M. at McGill, Faculty of Medicine, Montreal (1965), and interned at Royal Victoria Hospital, Montreal (1965-66). He received his M.P.H. (1969) and Dr.P.H. (1974) from the Harvard School of Public Health. Between 1970-1973 he served as a Research Fellow at the International Center for Medical Research and training, Cali, Colombia (Tulane University). During those same years he was a Research Fellow at the Harvard School of Public Health. In 1972-73, he was a Visiting Assistant Professor in Epidemiology, in the Department of Social Medicine, Universidad del Valle, Cali, Colombia. Between 1973-75, Dr. Neutra was an Instructor in the Department of Preventive and Social Medicine at Harvard

Medical School and a Visiting Lecturer, Spanish Epidemiology, Course for Professors of preventive Medicine, Federations of Pan American Faculties of Medicine, Bogota, Mexico City. He served as an Assistant Professor, Department of Epidemiology from 1974-1977 at the Harvard School of Public Health and from 1975-1977 as Assistant Professor, Department of Preventive and Social Medicine, Harvard Medical School. He became an Associate Professor, Division of Epidemiology, UCLA School of Public Health and Director, UCLA-Milbank, Program in Epidemiology and Health Policy (1977-1980). He was Associate Professor, Department of Medicine, UCLA Medical School (1978-1980) and Associate Director for Research, Center for Health Enhancement, Education and Research, UCLA Medical School (1978-1979). In 1980-1981, he served as Senior Epidemiologist, Epidemiological Studies Section, California Department of Health Services and has served as Lecturer in Epidemiology, University of California School of Public Health from 1981 to present. He served as Chief, Special Epidemiological Studies Program, California Department of Health Services from 1981-1982 and Chief, Exposure Assessment Section, California Department of Health Services from 1992 to present.[4] Additionally, he is currently Acting Chief, Environmental Health Investigations Branch, California Department of Health Services. Dr. Neutra is a past President of the International Society for Environmental Epidemiology, a member of the American College of Epidemiology, the International Society of Exposure Assessment, the American Epidemiological Society, International Epidemiological Association, Society for Epidemiologic Research and the American Public Health Association. He is board certified in Preventive Medicine, a Diplomate of the National Board of Medical Examiners and a Licentiate of the Medical Council of Canada. He has written many articles in the field of Epidemiology and Preventive Medicine with an emphasis in evaluation of medical technology, decision analysis, and

[4] Dr. Neutra is appearing as amicus in his own behalf and not as a representative of any governmental agency.



environmental epidemiology as applied to regulatory decisions.

**Dr. Stellman** received his B.Sc. in chemistry from Ohio State University in 1966, his Ph.D. in physical chemistry from New York University in 1971, and an M.P.H. in health policy and management from Columbia University in 1992. He was also a post-doctoral fellow in biochemical sciences at Princeton University in 1971-3 and Lecturer in Chemistry at the University fo Colorado at Denver in 1974. From 1975-80 he was Chief, Division of Computing and Biostatistics with the American Health Foundation in New York, where he directed numerous epidemiological studies of cancer with respect to environmental and lifestyle factors.

From 1980 through 1988 he was Assistant Vice President for Epidemiology with the American Cancer Society's national office, where he was Associate Director of Cancer Prevgention Study II, a six-year prospective study of mortality in 1.2 million American men and women and the largest such epidemiological study ever undertaken. In 1988 he became Assistant Commissioner of Health for Biostatistics and Epidemiologic Research for the City of New York, with administrative responsibility for registration of births and deaths, and as Director of the Bureau of Vital Statistics had scientific responsibility for records-based research on birth outcomes, such as birth defects. As Assistant Commissioner he was also editor-in-chief of *New York City Vital Statistics*, and had responsibility for the Office of Epidemiologic Research. During this period he directed studies in numerous areas of epidemiology, including infectious and chronic diseases, tuberculosis, prison health, cancer and the environment, maternal and child health, and AIDS.

In 1991 he returned to the American Health Foundation as a Senior Research Scientist where he is the chief epidemiologist for studies of tobacco-related cancers. He is also working at the International Agency for Research on Cancer in Lyon, France, as an NIH Fogarty International Fellow studying cancer in Asian immigrants to New York City. He has recently completed a master's degree in public health at Columbia University.

Dr. Stellman has published over sixty papers in epidemiology and health sciences, and another twenty-six in biophysical chemistry. He is a member of numerous professional associations,

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